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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,715	01/21/2004	Mark E. Cook	960296.00143	3715

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EXAMINER	
SZPERKA, MICHAEL EDWARD	
ART UNIT	**PAPER NUMBER**
1644	

NOTIFICATION DATE	DELIVERY MODE
07/11/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pat-dept@quarles.com

Office Action Summary	Application No.	Applicant(s)	
	10/761,715	COOK ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-13 and 17-28* is/are pending in the application.

4a) Of the above claim(s) *11 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5-10, 12, 13, 17-22, and 24-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response and amendments received April 24, 2007 are acknowledged.

Claims 2-4 and 14-16 have been canceled.

Claims 27 and 28 have been added.

Claims 1, 5-13 and 17-28 are pending in the instant application.

Claims 11 and 23 stand withdrawn from consideration as being drawn to a nonelected invention. See 37 CFR 1.142(b) and MPEP § 821.03, for reasons of record set forth in the restriction requirement mailed September 26, 2006.

Claims 1, 5-10, 12, 13, 17-22 and 24-28 are under examination as they read on methods of administering anti-PLA_2 antibodies that improve body weight uniformity and carcass yield.

2. The declaration under 37 CFR 1.132of Mingder Yang, a coinventor of the instant application, is acknowledged. The significance of this declaration will be addressed in conjunction with applicant's arguments concerning the rejections of record discussed below.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The rejection of claims 1-3, 5-10, 13-15, 17-22, 25, and 26 under 35 U.S.C. 112, first paragraph, lack of enablement has been withdrawn in view of applicant's claim amendments received April 24, 2007.

Specifically, applicant has amended the independent claims to replace the recitation of "agents" with "anti-phospholipase A_2 (anti-PLA_2) antibody".

5. The rejection of claims 1-3, 5-10, 13-15, 17-22, 25, and 26 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn in view of applicant's claim amendments received April 24, 2007.

Specifically, applicant has amended the independent claims to replace the recitation of "agents" with "anti-phospholipase A_2 (anti-PLA_2) antibody".

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 5-10, 12, 13, 17-22 and 24-26 stand rejected and new claims 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6,213,930 (of record on the 4/29/04 IDS, see entire document) for the reasons of record.

The office action mailed January 24, 2007 states:

> The '930 patent teaches methods of administering anti-phospholipase A_2 (anti-PLA_2) antibodies to animals to enhance animal growth and feed efficiency. This patent teaches that PLA_2 cleaves the covalent bond between arachadonic acid and membrane phospholipids, thus releasing arachadonic acid to serve as a prostaglandin/leukotriene precursor (see particularly lines 44-50 of column 1). Note that anti-PLA_2 antibodies are disclosed as inhibiting the activity of PLA_2 which thus effectively limit the bioavailability of arachidonic acid (see particularly lines 25-51 of column 2). Animals to be administered anti-PLA_2 antibodies comprise chickens, ducks, turkeys, quail, geese, cows, sheep, pigs, and goats (see particularly lines 8-13 of column 3). The anti-PLA_2 antibodies are administered by a variety of routes, comprising subcutaneously, intraperitoneal, intramuscular, intravenous, and oral, with the oral route being preferred (see particularly lines 52-62 of column 3). The '930 patent further teaches that anti-PLA_2 antibodies can be obtained from the yolk of immunized chickens, and that egg preparations comprising the specific antibody are to be given as a supplement to the animal's diet (see particularly from line 63 of column 3 to line 22 of column 4).
>
> It is noted that the preamble of the instant claims recite "improving body weight uniformity" and "increasing carcass yield" and that these particular phrases are not found within the text of the '930 patent. However, the process steps of the instant claims comprise administering an agent, such as an anti-PLA_2 antibody, to an animal. These process steps are taught by the '930 patent as discussed above. As such it appears that improved body weight uniformity and increased carcass yield are inherent benefits that accrue to an animal upon performance of the methods of administering anti-PLA_2 antibodies disclosed in the '930 patent. Applicant is reminded "[T]he discovery of a previously unappreciated property of a prior art composition (method), or of a scientific explanation for the prior art's functioning, does not render the old composition (method) patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Further, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but

only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also Toro Co. v. Deere & Co., 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004)("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention.").

Given that the same agent is administered to the same patient population, the methods of the '930 patent anticipate the claimed invention.

Applicant's arguments filed April 24, 2007 have been fully considered but they are not persuasive. Applicant argues that the prior art does not anticipate the claimed methods because the prior art does not administer sufficient antibody to observe improved body weight uniformity or carcass yield. Applicant supports this argument with the declaration under 37 CFR 1.132 of coinventor Mingder Yang which purports to show that when chickens are fed the amounts of anti-PLA2 antibodies disclosed in the working examples of the '930 patent, statistically significant increases in body weight uniformity were not observed.

This argument is not persuasive because applicant is arguing limitations that are not claimed. Specifically, neither the patented claims nor the instant pending claims recite any dosages to be administered. Claims are limited by what they recite, not what is disclosed in the specification.

Further, given that the same agent (anti-PLA_2 antibodies) are administered to the same population (captive-raise chickens) by the same route of administration (mixed into animal feed), any observed phenomena, such as increased growth, decreased gastrointestinal inflammation, enhanced carcass yield, and improved body weight uniformity are inherent since the recited method steps are the same. Note that as part of the administration process, a skilled artisan would need to observe the animals and as such a positive recitation that the animals are observed, such as appears in new claims 27 and 28 is not accorded patentable weight.

The rejection is maintained.

8. Claims 1, 5-10, 12, 13, 17-22 and 24-26 stand rejected and new claims 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6,383,485, (see entire document) for the reasons of record.

The office action mailed January 24, 2007 states:

> The '485 patent teaches methods of administering anti-phospholipase A_2 (anti-PLA_2) antibodies to animals to enhance animal growth and feed efficiency. This patent teaches that PLA_2 cleaves the covalent bond between arachadonic acid and membrane phospholipids, thus releasing arachadonic acid to serve as a prostaglandin/leukotriene precursor (see particularly lines 46-51 of column 1). Note that anti-PLA_2 antibodies are disclosed as inhibiting the activity of PLA_2 which thus effectively limit the bioavailability of arachidonic acid (see particularly lines 26-53 of column 2). Animals to be administered anti-PLA_2 antibodies comprise chickens, ducks, turkeys, quail, geese, cows, sheep, pigs, and goats (see particularly lines 10-15 of column 3). The anti-PLA_2 antibodies are administered by a variety of routes, comprising subcutaneously, intraperitoneal, intramuscular, intravenous, and oral, with the oral route being preferred (see particularly lines 52-63 of column 3). The '485 patent further teaches that anti-PLA_2 antibodies can be obtained from the yolk of immunized chickens, and that egg preparations comprising the specific antibody are to be given as a supplement to the animal's diet (see particularly from line 64 of column 3 to line 22 of column 4).
>
> It is noted that the preamble of the instant claims recite "improving body weight uniformity" and "increasing carcass yield" and that these particular phrases are not found within the text of the '485 patent. However, the process steps of the instant claims comprise administering an agent, such as an anti-PLA_2 antibody, to an animal. These process steps are taught by the '485 patent as discussed above. As such it appears that improved body weight uniformity and increased carcass yield are inherent benefits that accrue to an animal upon performance of the methods of administering anti-PLA_2 antibodies disclosed in the '485 patent. Applicant is reminded "[T]he discovery of a previously unappreciated property of a prior art composition (method), or of a scientific explanation for the prior art's functioning, does not render the old composition (method) patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Further, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also Toro Co. v. Deere & Co., 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004)("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention.").
>
> Given that the same agent is administered to the same patient population, the methods of the '485 patent anticipate the claimed invention.

Applicant's arguments filed April 24, 2007 have been fully considered but they are not persuasive. Applicant's argument is the same as that discussed above concerning the anticipation of the instant invention by the '930 patent. This issue is adequately addressed above and will not be addressed further.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1, 5-10, 12, 13, 17-22 and 24-26 stand rejected and new claims 27 and 28 are rejected under on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,213,930. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims anticipate the instant invention for the reasons of record. The office action mailed April 24, 2007 states:

> Specifically, patented claim 1 recites "administering to said animal an agent that reduces the bioavailability in the animal of a prostaglandin or leukotrienes lipid precursor, wherein the agent comprises an antibody". The independent claims in the instant application are not limited to administering antibodies, and as such the patented method claims anticipate the instant invention. Note that dependent patented claims recite anti-PLA_2 antibodies, that mammals such as cows and avians such as chickens are subjects for antibody administration, and that the antibodies can be administered by various injection routes or orally mixed with food, such as an egg preparation that comprises antibodies.
>
> It is noted that the patented claims recite that the antibodies are administered to "enhance growth and feeding behavior" while the instant methods are recited as "improving body weight uniformity" and "increasing carcass yield". However, as discussed above, the antibodies administered in the patented claims anticipate the instant recited genus of administered agents and the populations to whom the agents are administered are not distinctly different. Therefore, "improved body weight" and "increased carcass yield" are inherent properties that arise when the patented method is performed in an animal.
>
> Applicant is reminded "[T]he discovery of a previously unappreciated property of a prior art composition (method), or of a scientific explanation for the prior art's functioning, does not render the old composition (method) patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Applicant's arguments filed April 24, 2007 have been fully considered but they are not persuasive. Applicant's argument is that performing the methods claimed in the

'930 patent does not yield improved body weight uniformity, and argues that that the declaration under 37 CFR 1.132 of coinventor Mingder Yang supports this argument.

This argument is not persuasive for the reasons discussed above in conjunction with the anticipation of the instant invention by the '930 patent.

The rejection is maintained.

11. Claims 1, 5-10, 12, 13, 17-22 and 24-26 stand rejected and new claims 27 and 28 are rejected under on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,383,485. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims anticipate the instant invention for the reasons of record. The office action mailed April 24, 2007 states:

> Specifically, patented claim 1 recites "administering to said animal an agent that reduces the bioavailability in the animal of a prostaglandin or leukotrienes lipid precursor, wherein the agent comprises an antibody". The independent claims in the instant application are not limited to administering antibodies, and as such the patented method claims anticipate the instant invention. Note that dependent patented claims recite anti-PLA_2 antibodies, that mammals such as cows and avians such as chickens are subjects for antibody administration, and that the antibodies can be administered by various injection routes or orally mixed with food, such as an egg preparation that comprises antibodies.
>
> It is noted that the patented claims recite that the antibodies are administered to "reduce gastrointestinal inflammation" while the instant methods are recited as "improving body weight uniformity" and "increasing carcass yield". However, as discussed above, the antibodies administered in the patented claims anticipate the instant recited genus of administered agents and the populations to whom the agents are administered are not distinctly different. Therefore, "improved body weight" and "increased carcass yield" are inherent properties that arise when the patented method is performed in an animal.
>
> Applicant is reminded "[T]he discovery of a previously unappreciated property of a prior art composition (method), or of a scientific explanation for the prior art's functioning, does not render the old composition (method) patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Applicant's arguments filed April 24, 2007 have been fully considered but they are not persuasive. Applicant's argument is that performing the methods claimed in the '930 patent does not yield improved body weight uniformity, and argues that that the declaration under 37 CFR 1.132 of coinventor Mingder Yang supports this argument.

This argument is not persuasive for the reasons discussed above in conjunction with the anticipation of the instant invention by the '930 patent.

The rejection is maintained.

12. No claims are allowable.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Szperka, Ph.D.
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June 25, 2007

7/1/07
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER